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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/870,203 | 05/30/2001 | Paul L. Hallenbeck | 4-31452A | 7861 |
| 1095 | 7590 | 11/03/2003 | EXAMINER | |
| THOMAS HOXIE NOVARTIS, CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080 | | | HILL, MYRON G | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1648 |

DATE MAILED: 11/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/870,203 | HALLENBECK ET AL. | |
| Examiner | | Art Unit | |
| Myron G. Hill | | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 June 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8- 62 is/are pending in the application.
- 4a) Of the above claim(s) 8- 32 and 37- 62 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 33- 36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This action is in response to paper filed 16 June 2003.

Claims 33- 36 are under consideration, claims 1- 7 were cancelled, and claims 8-32 and 37- 62 are withdrawn.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged.

The traversal is on the ground(s) that the invention is a combination/subcombination and the combinations should be examined together. This is not found persuasive because the subcombination is distinct and not allowable as indicated in paper #11.

Applicant continues to assert that the restriction is improper because predetermining of allowability is not a requirement for examining subcombination and combination inventions together, that two-way distinctness was demonstrated here, and that the subcombination and combination inventions should be examined together. The restriction is based on patentable distinctness as shown in the restriction requirement and agreed to by Applicant in acknowledging two-way distinctiveness, and thus the inventions can be examined individually. See M.P.E.P. 806.05(c):

Criteria of Distinctness for Combination, Subcombination, or Element of a Combination- In order to establish that combination and subcombination inventions are distinct, two-way distinctness must be demonstrated.

The restriction is not based on allowable claims or combinations. Allowability of the subcombination is what permits rejoinder, not the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Rejections Withdrawn

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn because of cancellation of claims or amendment.

Rejections Maintained

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33- 36 are rejected under 35 U.S.C. 102(e) as being unpatentable over Wickham.

The claims are drawn to a mutant Adenovirus Type 5 fiber protein comprising mutations at positions 408 and 409.

Applicant argues that Wickham only provides a long list of possible mutations and does not teach those specific positions as well as that Wickham discloses in vivo results that are different from those observed by Applicant.

The arguments have been fully considered and not found persuasive.

The argument that Wickham does not disclose the specific combination and that Wickham teaches a possible 32,767 combinations is not persuasive because the MPEP states that a reference that clearly names the species anticipates the claim no matter how many other species are named (see MPEP 2131.02 Genus-Species Situations- A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES ARE NAMED).

The argument of unexpected results that the product enhances gene transfer to liver cells and as disclosed in Smith (attached, not of record), and differ from results taught by Wickham is not found persuasive because the claims are drawn to a mutant adenovirus fiber protein, a product. Unexpected results are irrelevant to 35 USC 102 rejections, see MPEP 2131.04.

Claims 33- 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirby.

Applicant argues that Kirby does not disclose a double mutant and that the Examiner has not met the legal burden of obviousness or motivation and that the claimed product shows unexpected results in that the product enhances gene transfer to liver cells and cites Smith (attached, not of record).

Applicant's arguments have been fully considered and not found persuasive.

Kirby does not disclose a double mutant, thus the reference does not anticipate as required under 35 U.S.C 102. However, Kirby supplies motivation for the combination of mutations at positions 408 and 409 specifically in the last paragraph of

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page 2811- first line page 2812 where those two amino acids are named as being conserved in multiple serotypes of adenoviruses (Ad5, Ad2, and Ad9 fibers and long fibers of Ad40 and Ad41 which bind to CAR- coxsackievirus and Adenovirus receptor) but not conserved in fibers short fibers of Ad3 or Ad41 which do not bind CAR).

One of ordinary skill in the art at the time the invention was made would have been able to test multiple mutations using the methods of Kirby compare test structure/function of mutants to wild type to determine if they did not bind to CAR and still had the overall structure of an Adenovirus fiber protein.

Thus, knowing that both these residues are conserved and important for binding to CAR (Figure 3, lower left, and last paragraph of page 2811), one of ordinary skill in the art would be motivated to make a mutant that includes the two specifically named amino acid residues of 408 and 409 with the expectation of reducing binding of fiber protein to CAR over a mutation at just one position because both are identified as important in CAR binding and one would expect at least an additive effect.

The argument of unexpected results that the product enhances gene transfer to liver cells and as disclosed in Smith (attached, not of record), is not found persuasive because the claims are drawn to a mutant adenovirus fiber protein. The claims are not drawn to methods of enhancing gene transfer to liver cells. The discovery of a characteristic of a known structure is presumed inherent. See MPEP citation below:

2112.01 Composition, Product, and Apparatus Claims

PRODUCT AND APPARATUS CLAIMS - WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

Thus, Kirby did make obvious and provide motivation for mutations at positions 408 and 409 and the *in vivo* function of the double mutation would be inherent property of the product.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
October 10, 2003



JEFFREY STUCKER
PRIMARY EXAMINER